STATE MEDICAID DUR BOARD MEETING
THURSDAY, July 10, 2008
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

MINUTES

Board Members Present:
Mark Balk, Pharm, D.
Derek Christensen, R.Ph.
Dominic DeRose, R.Ph.
Joseph Miner, M.D.
Conlin VanOrman, M.D.
Neal Catalano, R.Ph.
Tony Dalpiaz, Pharm.D.
Bradford Hare, M.D.
Bradley Pace, PA-C
Joseph Yau, M.D.

Board Members Excused:
Don Hawley, D.D.S.
Wilhelm Lehmann, M.D.

Dept. of Health/Div. of Health Care Financing Staff Present:
Suzanne Allgaier, R.N.
Tim Morley, R.Ph.
Duane Parke, R.Ph.
Jennifer Zeleny, CPhT
Richard Sorensen, R.N.
Merelynn Berrett, R.N
Lisa Hulbert

Other Individuals Present:
Jeff Buel, J&J
David Mostellar, Romark
April Pallesen
Lori Howard, Bayer
Darlene Benson, R.N.
M. Roundy, M.D.
Tony Molchan, Abbott
Jen Kammerer, AZ
Adam Sosa, Janssen
Trish McDaid-O'Neill, AZ
Dr. Tom Jones
Barry Osborne, Romark
David McAfee, U of U
David Lindquist, Janssen
Gloria Tolla, RN - UUHP
Michael Stevens, M.D.

Meeting conducted by: Colin VanOrman, M.D.

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1. Minutes for May 8, 2008 were reviewed, corrected and approved. Mark Balk moved to accept the minutes as corrected. Dr. Miner seconded the motion. The motion passed with unanimous votes by Mark Balk, Neal Catalano, Derek Christensen, Tony Dalpiaz, Dominic DeRose, Dr. Hare, Dr. Miner, Bradley Pace, Dr. VanOrman, and Dr. Yau.

2. Invega: Craig Bernson, Pharmacy Director from Utah State Hospital addressed the Board. A memo was provided to Tim Morley approximately 1 month ago. This memo was given to the DUR Board in the information packet. Invega has two significant advantages over Risperdal, which it was intended to replace. One is the timed release oral delivery vehicle. Because of the timed release delivery vehicle, it has a better pharmacokinetic profile and

better side-effect profile. In fact, it appears to be tolerated better than Risperdal, particularly with the side-effects as it relates to EPS. The other reason is that Invega is metabolized risperidone. Because it is already metabolized, it is minimally involved in hepatic metabolism. This has two advantages. First, it has fewer drug-drug interactions. Most patients who are on an atypical antipsychotic are not on monotherapy. The other advantages is that patients who have hepatic impairment have an advantage in taking this medication. A number of patients at the hospital have Hepatitis B or Hepatitis C and already have hepatic impairment. A third point that was made in the memo is that Invega compares very favorably in the cost profile to other second generation antipsychotic drugs. Because there is a great lack of homogeneity in this category of drugs, this category of medication needs to be left open for all agents. It is of concern that the patients in the hospital are stabilized on Invega, once they leave the hospital there may be a disruption in the continuity of care if they have to have PA.

Dr. Stevens, Medical Director of Davis Behavioral Health, addressed the Board. In the broad group of medications called second generation antipsychotics, this medication has 3 qualities for improving access to it over any of the others. The cost is a very significant one. Certainly it is one of the less expensive agents in this group. The second is that the 6mg dose, which is effective in the real world, actually has a profile that is cleaner for metabolic syndrome than all but possibly one other agent in this group. People think of paliperidone as being a "me-too" drug with risperidone. The reality is that psychiatrists know imipramine/desipramine or amoxapine/loxapine. There are a number of drugs in psychiatry where the first metabolite is not biologically all that similar to the parent compound. There is some evidence that even in the brain this drug functions significantly differently in terms of dopamine receptors than risperidone does. Comparing it to other second-generation antipsychotics in terms of access, looking at the problem of motor side-effects, this is an area in which risperidone has been very problematic. Paliperidone has a far better profile at 6mg. People with psychotic illness are often on many medications, and the relative absence of hepatic interactions is very important. Better access will allow professionals to treat more cost-effectively.

Scott Roundy, psychiatrist in the Ogden Area, addressed the Board. Invega is as effective, if not more effective, than any other atypical. In general, with increased efficacy there are increased metabolic difficulties. A big advantage of Invega is that it is very efficacious and metabolically friendly. He has had many ill patients who have gotten better and then gained 20-40 pounds, gotten diabetes, and then had to go to some other treatment. This does not seem to be the case with Invega. The hepatic profile is good, so it is the drug of choice for patients with Hepatitis. The patients that he has used it on have been fairly treatment-resistant. He has chosen Invega in those patients because he can justify the pre-authorization. These are patients who have failed on multiple other medications, but have not failed on Invega. He also has yet to have problems with metabolic syndrome. He had one patient who began to lactate on 9mg, but did not want to change to another drug because she had failed on other drugs. A lower dose of 6mg improved the problem. He has also used it in major depressive disorder, schizoaffective disorder, and mania with good results. Pre-authorization should not be required. It is difficult for providers to get pre-authorization, and it is disruptive to care.

Sherri Wittwer, Executive Director of NAMI Utah addressed the Board. NAMI is the National Alliance on Mental Illness. NAMI is an organization that advocates from the perspective of individuals who are personally effected by mental illness and their families.

NAMI has an interest in maintaining open and unrestricted access for mental health medications for those who need them. This is a policy that they advocate for because psychotropic medications such an important role in a person's recovery and for their ability to live full and productive lives in the community. The information and policies that NAMI advocates for only come from the leading researchers in the nation. The National Institutes for Mental Health reports that individuals have unique responses to psychiatric medications and need more, not fewer, choices. They further stated that a medication that works well for one person with schizophrenia often doesn't work well for another. Genetic variations are thought to play a key role in this difference in response. While patients search for the right medications, their illnesses may worsen. Utah's State Legislature recognizes the vital role of medications used to treat mental illness and the cost implication of imposing barriers to treatment. In 2007, the Legislature adopted language with the intent of exempting the full range of psychiatric medications from the Medicaid Preferred Drug List. In May 2007, the Executive Appropriations Executive Committee voiced concern about preauthorization practices and fail-first policy. And yet, we have a preauthorization practice in place for an antipsychotic medication. Still, what is most concerning about this policy is the ramifications for the people represented by NAMI. NAMI has received letters from the Utah State Hospital in which providers have stated their concerns about limiting access to Invega. A number of patients are currently using Invega at the State Hospital and are finding success with this medication. These experts are concerned about their patients being able to access Invega when they are back in the community. This concern appears to be well-founded given the other letters and phone calls received from the public mental health centers. They are finding that individuals with serious mental illness who are currently doing well on Invega are unable to get this medication using their Utah Medicaid. One letter states, "In our opinion, there is a clinical need for this drug, and the authorization process is not working to get these patients the medication they need." From NAMI's perspective, there is no explanation that can justify withholding treatment that has been proven to work with people with schizophrenia and force them to try other medications at the risk of failure. No policy should override the clinical judgement of the State Hospital or public mental health centers who work with these patients and take into account their histories and individual recovery plans. NAMI will always be consistent in the belief that people with mental illness must have unrestricted access to the medications that they need.

Adam Sosa, Scientific Liason with Ortho-McNeil-Janssen, addressed the Board. The drug is an active metabolite, but what simply cannot be lost is the clinical relevance of the differences in pharmacokinetic profile and the metabolism of the drug. How this metabolite acts in vivo is significant around drug-drug interactions, and in potentially minimizing the effects of tolerability discontinuations with the Oros system that minimizes the peaks and troughs so that the patient is not on the roller coaster ride of drug therapy. Specific around those metabolites, it can be likened to Seldane prodrug terfenidine. Today, a very successful antihistamine is fexofenadine. It acts very differently and is a very effective antihistamine. A metabolite simply cannot be considered a "me too" product. There is also a growing body of evidence in literature nationwide of state Medicaids, specifically Maine Medicaid, that looked at step therapy PA processes and the impact it had in restricting patient care. What the authors concluded at the end of the study was that the PA process had an all-cause discontinuation rate of about 29%. A lot of the clinical discussion has already been addressed by physicians in practice with patients. He will answer any questions regarding the pivotal trials, safety, or effectiveness of the drug.

Dr. Yau stated that risperdal is already off patent. The cost comparison of this drug to

Zyprexa and other agents is impressive. The metabolism and lack of drug interactions is a valid point. He asked if the improvement on Invega versus other agents is due to adherence to the once daily dosing, even though the State Hospital probably doesn't have issues with adherence while patients are in house.

Craig Bernson stated that the State Hospital does not have problems with compliance and adherence while patients are in-house, but every consideration is given to when they leave. The State Hospital wants to simplify their drug regimen in order to minimize problems with adherence. Adherence is low anyway. With single daily dosing and improved tolerability, patients are more likely to take it, particularly if they feel that they are achieving a benefit from the medication.

Adam Sosa responded to Dr. Yau's question regarding Invega versus Risperdal. There is data on file where a post-hoc analysis was done of patients previously treated with Risperdal. There was a washout period where the patients were then randomized into a double-blind placebo-controlled study. In that study, there were some improvements. These were patients who had some exacerbations of schizophrenia, so one could make the assumption that they were either failing Risperdal or they were not tolerating it. There was some improvement in total PANSS scores in positive and negative symptom scores for patients who were previously on Risperdal and then given Invega.

Dr. Yau stated that one of the three criteria was whether the PA would impact care. This is valid concern that has been raised.

Rep Ray: My name is Paul Ray. I am a member of the House of Representatives, Chairman of the Health and Human Services, and sit on the Health and Human Services Appropriations Committee. As a legislature, we made it very clear that we did not want these types of drugs put into any type of a PDL or a Prior Authorization, and I find this kind of a slap in the face to the legislature that we're using the DUR Board to go around the PDL. And, uh, be careful how you act today and what decisions you make, because we'll deal with it. It's not within this board's authority to do that, and I find it very, very irritating, after all the negotiations that we did with the Department of Health to come here today and see this happening.

Tim Morley: May I address your comments, Mr. Ray?

Rep Ray: You bet.

Tim Morley: The action that the Board took with Invega predated the legislation of the Utah Legislature.

Rep Ray: It did, but the legislature prior, or, since that fact has said as in the last year we don't want these types of drugs handled this way. I can see the end around. I'm not stupid. So, like I say, please be careful what you do because there's no true proved savings for the PDL for prior authorizations. I know there's gonna be a major cost for what happens to people that are on these types of drugs. My wife's bipolar. I live this every day. And I know how important it is to find a medication that works and to stick, to stick to that medication. So, you know, these Medicaid people, the least we can do is give them the proper medication that they need in order to help them get, you know, to a semi-normal lifestyle. So, please, just be careful. And, uh, there's a lot of legislators

watching what's going on. We're aware of what's happening here, and that's why I'm here today. I was asked by fellow legislators to come and, you know, make the statement today and also to just kinda watch what goes on here. Thank you.

Tim Morley: Thank you. Just like I say, there was no end around, because the law didn't exist. So we didn't know we were trying to get around a law that didn't exist. We were trying to do due diligence with what we've been assigned to do statutorily and legislatively as well. The reason that this is brought back today, let me give you a little bit of background, is because of complaints by the PhRMA community, objections raised by them to the particular Prior Authorization process for which Invega came under. We have restructured the manner in which we are to, at the direction of the Assistant Attorney General's office, Doug Springmeyer here, who is with the Department of Health, that we do need to proceed along a prescribed path when we consider particular medications, particularly the Prior Authorization. There is a statute regarding Prior Authorizations that specifies what we can consider and what we should consider. This new format for the information in your packets outlines that new process. And so, when we discuss an issue, we need to look at each one of these sections that's in this process. So, if you've got your Invega packet in front of you, we have, first of all, the description of the problem. The second section deals with usage data. And, during the Prior Authorization process, we can only place a Prior Authorization for clinical reason. So, cost data cannot be part of that discussion, so you'll notice there's no cost data or savings information as far as the issue goes for the state. So we look at the usage data, and as Invega's concerned, for 2007-2008 we have 63 unduplicated users of Invega. Information for Risperdal, which is the associated drug, is on the next page 2 of 26. We have 2,961 unduplicated users. Section PA.3, which deals with supporting studies and other data compiles information that I could find regarding Invega. The information from the manufacturer itself did not list many differences between Invega and Risperdal, in terms of efficacy or safety, save in one case where there was a higher incidence of cardiac effects with Invega. It is true that Invega is a little bit easier to dose, but the information from the manufacturer itself didn't differentiate between them much at all. The other information here, articles from some other specialists and some studies, and I won't summarize or go through each one of those. If we go next to section PA.4, there's no information from the University of Utah or a criteria study that we have. Public and expert testimony: I've included letters that were written, and we've heard from some professional individuals who requested time to address the Board on this issue today. And then, the next section, which is on page 24 of 26, we come to the Division recommendation criteria. And we are simply recommending today that the criteria for Invega be re-evaluated based on its clinical provisions, regardless of cost, and a determination made as to whether or not a PA is valid on that basis. The clinical reasons for the PA need to be specifically mentioned and the findings listed in section PA.7 noted. So, the criteria for Invega are as follows: minimum age 18 years old, that's an FDA approved limitation; diagnosis of schizophrenia, that's the only indication for which it is approved; and the third criteria is that the patient cannot tolerate a single daily dose of risperidone. Those are the three criteria for the PA on Invega. Section PA.7: this drug or drug class may not be placed on PA for other than medical reasons, and we need to find an answer or a specific finding for the following three areas. So 7.1, does the board conclude based on the foregoing discussion and testimony that the PA will not impede the quality of care? So that would need to be an area of discussion for the Board. And we would need to evidence that support. 7.2, does the Board conclude based on the foregoing discussion and testimony that the drug class is subject to clinical abuse or misuse? And 7.3, does the Board conclude that there is a medical reason

for a PA? Unless we have an affirmative answer to all three of those questions, then the PA cannot be placed. So, this is the format for discussion for the Prior Authorization. And those are the elements that we would need to discuss at this point. So, I would invite the Board and open the discussion at this time, as it regards those three areas. If you have comments, let's open the discussion now and have any comments from the Board at this point.

Dr. VanOrman: Am I to understand that any discussion of Prior Authorization is pointless when it comes to psychotropic medications? So, is that what the law says?

Board Member (Derek?): Sounds like it.

Tim Morley: The law, in connection with the Preferred Drug List, the legislature directed that the Preferred Drug List not be enforced with a Prior Authorization. And then they exempted specifically psychotropic medications from the PDL.

Mark Balk: So the law, in the past, has not included the DUR and was specific to the P&T, but it is nice to have the clarification that the intent or the spirit of that law is not to break Medicaid into the P&T and the DUR, but to think of it, in this case, as one body. So, with that being said, I would agree, I guess. I would lean towards that it is almost a moot point, although I do like the format and we'll use it for the other products as we go through the agenda.

Tim Morley: OK, we have to have evidence supporting a conclusion of each one of those areas from the discussion of the Board. So, I would suggest that does the Board conclude based on the discussion and testimony that the PA will not impede the quality of care? Does anyone have any comments or viewpoints on that point?

Dr. Miner: Well, I think based on the testimony of our pharmacists and physicians that, which I appreciated a lot, that our answer to 7.1 be no.

Board Member (Derek?): I agree.

Dr. Miner: And 7.2 be maybe, and 7.3 would be no.

Dr. VanOrman: Any other? Is that a motion?

Dr. Miner: That would be my motion to drop the PA.

Mark Balk: I'd second that.

Dr. VanOrman: I just have one other question Mr. Ray. Does that mean that there is no limitation… I mean, right now, like the minimum age and the diagnosis of schizophrenia that is not also allowed. I mean, it can be used for any age, any diagnosis, that the legislature does not want any restriction under any circumstance for any use of the drug? Is that my understanding?

Paul Ray: Yeah, that's our understanding. There has been legislation filed last year and again this year to kinda clarify that a little bit. But at this point there's not been a complete clarification on that. But Dr. Christensen, who is a senator from North Ogden is

trying to get better clarification. At this point, how we view it is that it should be... And again, I guess it's not clear. Let's just say it's a grey area. It's up for argument. And we're trying to clarify it one way or the other at this point.

Dr. VanOrman: So the FDA indications, is that a shield for the physicians, then? They don't need to abide by the FDA regulations? The medications are open for anybody for any use is the intent?

Paul Ray: Well I guess my problem is telling doctors how to do their job.

Derek asked if the legislation that was passed last spring only applied to the PDL. Tim Morley stated that it was passed in connection with the PDL. Derek asked how that is distinguished from the work that is done on the DUR Board. Tim stated that the DUR Board is an extension of the Division of Health Care Financing. There is a dual legislative mandate and they utilize the DUR Board for most of what they do. The legislation that was passed last spring was specific to the PDL. Out of that grew the P&T Committee, which considers issues specifically for the PDL. In connection with that, the Legislature also directed that certain drugs not be included on a PDL. They also directed that it not be enforced with a PA. "Psychotropics" was one of the excluded drugs for the PDL. Derek asked if it would still fall under the DUR Board's purview. It would if it were considered for PA, but not if it were being considered for a PDL, which, for psychotropics, the Division does not have. This drug was put on PA before the PDL legislation was considered. Part of the issue is that the Division did not understand that the Legislation was intended to destroy everything that was done previously. It was understood to apply to the PDL and to those issues surrounding that legislation at that time. Because of that, the PA on Invega went forward. Since then, objections have been raised from the PhRMA community as to whether or not the PA specifically for Invega was appropriate. In light of everything else, the PA can be removed if that's what needs to be done. The Division will remove the PA if that is the consensus of the Board. This is why the Board exists. Specifically, when a PA needs to be done the Board needs to consider clinical reasons.

Derek wanted to elucidate. It seems to be a matter of perception whether the legislation that was enacted last spring was retroactive or not. This is part of the issue. The Division needs to interpret laws and rules every day in order to administer the program. This program comes with significant Federal rules, laws, and regulations. When they conflict on a State level, it is difficult to get them to correlate well. This is one of the reasons that Invega is being brought back. Perhaps the wrong step was taken with Invega for clinical reasons. The Board should go back through the steps on it to see if it should be or should not be on PA. This is why the Division has designed the discussion template to avoid these problems in the future.

Dr. Hare asked if this legislation is going to hamper or handcuff the DUR Board so severely that they will not be able to function. It sounds like if someone makes a plea on something that the Board thinks should be a PA drug, the Board will be told that it can't be limited. Is the Board's input really going to be useful? Is the Board going to be able to provide meaningful input? Can the Board function?

Tim stated that his answer would be to direct the discussion to the template that contains the three findings that must be established. A PA can be placed if the Board establishes

that the PA will not impede the quality of care in section 7.1, if the Board establishes that the drug class is subject to clinical abuse or misuse, and if the Board concludes that there is a medical reason for the PA (i.e. a difference in side effect profiles, whether it is a meaningful addition). Dr. Miner added that some drugs can even be harmful to public health if certain things haven't been checked prior to starting therapy. Like with the anti-TNF's, there are some specific things that need to be checked and need to be added to PA criteria.

Dr. Yau asked what exactly is clinical abuse or misuse? Tim stated that this is a discussion that the Board should have. The Board felt that if this included off-label use, that could be included. Certainly for drugs such as Invega, off-label use is a big concern. However, what is an FDA approved indication is certainly not a limit on what is a clinically appropriate use.

Duane stated that the Federal OBRA law does state that Medicaid needs to abide by FDA indications. Medicaid is subject to Federal laws, and 75% of Medicaid funds are Federal dollars. State funds make up 25% of Medicaid funds. He has been advised by lawyers that when laws conflict, the more stringent laws apply.

Tim stated that in order to be on safe ground, the discussion needs to center on the three points in the discussion template.

The Board asked if they would be at risk if physicians wrote off-label for Invega. Tim stated that he needs to ask a legal specialist. However, it does put Medicaid at risk in a Federal audit if the Federal government were to find that claims were paid inappropriately. If the State law is more stringent, than certainly the Board needs to abide by it, but there is some question about whether or not one law preempts the other. This is a legal interpretation. The guidance from CMS is that they pay for FDA approved indications, and those off-label indications listed in one of the 3 compendia and supported by data. The question before this Board is whether or not this poses a problem for drug utilization, for public health, and whether or not this is a wise use of the medication. The Federal law states that medications cannot be paid for experimental or investigational uses. Many times, off-label use is experimental or investigational because the data has not been provided to get the approval from the FDA. There are always ongoing studies and ongoing efforts in the medical community to explore other uses, but until those become established in fact the Feds look at them as experimental or investigational.

The guidance that Medicaid has is that in order to do a PA for the Medicaid program, it needs to be based in the three areas in the discussion template. The Board is going to need to make a decision whether the FDA approval stands, or whether it makes sense to allow uses outside of the FDA approval. The information that is provided is what is available to aid in that decision.

The Board asked if there are edits in the system that will require a diagnosis code and age edits to ensure that the State laws are being met and FDA guidelines are being met. Tim stated that the only way to ensure this is with a PA.

Mark Balk stated that there are a lot of drugs that have not been studied in pediatrics. There would need to be PA's on almost all drugs to ensure that they are being used in the FDA approved age groups. The ages are provided in the PA guidelines as educational

tools when the drug is being put on PA anyway. The statute that was written when the DUR Board was put together is what requires the 3 components. The other piece of that is that there needs to be re-reviewed in 9 months. The more PA's that this Board puts on, the more work will be done in reviewing that PA in a 9 month time period.

Tim stated that the statute doesn't state that the PA needs to be reviewed every 9 months, it only states that it needs to be reviewed 9 months after it is placed.

There was a motion on the table to remove the PA made by Dr. Miner and seconded by Mark Balk. Mark Balk called for a vote on the motion. The motion passed with unanimous votes by Mark Balk, Neal Catalano, Derek Christensen, Tony Dalpiaz, Dominic DeRose, Dr. Hare, Dr. Miner, Bradley Pace, Dr. VanOrman, and Dr. Yau.

3. Opiate Analgesics: Discussion of the quantity limits was deferred until the following month. Some of the pharmacists on the Board were stating that claims were underpaying for Oxycontin even if it had the words "Medically Necessary - Dispense as Written" on the prescription and was submitted with the proper indicators for this. There are no generics currently available for Oxycontin. Medicaid clarified that Oxycontin prescriptions need "Medically Necessary - Dispense as Written" due to Oxycontin not being preferred on the PDL. The problem is a programming problem that will be fixed.

   Darlene Benson addressed the Board. The Prescription Task Force for the state will be coming out with new guidelines for acute and chronic pain within the next 6-8 weeks.

4. Arthritis/Plaque Psoraisis Biologic Immunomodulators Final Review of Criteria: Updated criteria sheets were provided to the Board. Mark Balk did go through the sheets carefully and had the following changes:

   Enbrel (page 10): The top of that needs to be like page 14 Remicaid and state for Rheumatoid, Psoriatic Arthritis, and Ankylosing Spondylitis at the top. On the first bullet point, on diagnosis rather than "severe" it is to state "moderate to severe". There should be the age of 18 on that one, too. On the very last bullet, it states that it should not be given with other biologic agents. That same type of verbage should be on all of them for consistency's sake. The verbage doesn't matter as much as the need for consistency.

   Humira (Page 11): Again at the very top, add that it's for Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis. Diagnosis needs to say "moderate to severe". Age 18 needs to be on this as well.

   Kineret (Page 12): At the top, just Rheumatoid Arthritis. Diagnosis needs to say "moderate to severe". Bullet point 3 on history of treatment failure... Needs to say "or" instead of "and at least". Again at the bottom, the verbage about Enbrel should be broadened to say "other TNFs"

   Orencia (page 13): Again, at the top "for Rheumatoid Arthritis". The age should be 18 years of age. The 6 would be appropriate for JIA, and a separate sheet needs to be created for JIA and state age 6. Refer to pages 20 and 21 for the format for JIA criteria.

   For authorization periods, there is some discrepancy. Is a trial period still needed? Should the authorization period be for 6 months or a year? This is more of a

departmental logistical issue than a clinical issue, but the Board felt that it should be standardized. Mark Balk felt that a 12 week trial and a subsequent authorization of 1 year for all of these agents would be appropriate, but suggested that Medicaid have that discussion internally.

Remicaid (page 14): It does have the diagnoses listed at the top. Age 18 should be on this. Bullet point 5 says "given in combination with methotrexate" and then goes on to have the same verbage at the other agents. At the bottom, it does say that it is not to be given with other biologics. In the packaging, it does specifically state that it is not to be given with Kinteret. This should be noted. The "every other week" comment should be stricken, since it is up to the provider how to dose it - there are various ways to do that.

Enbrel (page 15): Bullet point 1 should say "moderate to severe". The verbage in bullet 2 should be "at least one appropriate systemic agent or phototherapy". Bullet 3 about the 10% BSA should be stricken entirely. Age 18 needs to be on that one.

Humira (page 16): This is for Psoriatic arthritis. Bullet 1 should say "moderate to severe", verbage in bullet 2 same as Enbrel, bullet 3 to be dropped. The derm consult should stay on that. Age should be 18.

Amevive (page 17): Add plaque psoriasis at the top, and age 18. The verbage should be the same on the appropriate systemic agent or phototherapy, and the step therapy should be dropped completely.

Raptiva (page 18): Diagnosis should be changed to "moderate to severe". Bullet point 3 about the trial should be dropped, and replaced with verbage about appropriate systemic or phototherapy. Add at the top that this is the criteria for Plaque Psoriasis.

Remicaid (page 19): Diagnosis on bullet point 1 should be "chronic severe" since that is the approved indication. Change verbage on bullet 2. Age on this is 18 years.

Enbrel for JIA (page 20): Age is 2 years. Everything else looked good.

Humira fod JIA (page 21): No changes.

Remicaid for JIA (page 22): The age is 4 years or older. Everything else looked good.

Remicaid for Ulcerative Colitis (page 23): Age 18.

Remicaid for Crohn's (page 24): Age 6 and above.

Humira for Crohn's (page 25): Medicaid needs to look up the age on this indication and add it.

Dr. Miner added that if the patient has had a positive TB skin test, there needs to be documentation of treatment for latent TB infection. It should read "Negative TB skin test or history of treatment for latent TB infection".

Mark Balk recommended that points 7.1, 7.2, and 7.3 be discussed before a motion is made. The Board answered that the answer to all 3 questions is a "yes".

Derek moved that the criteria sheets be accepted as corrected. Dr. Miner seconded the motion. The motion passed with unanimous votes by Mark Balk, Neal Catalano, Derek Christensen, Tony Dalpiaz, Dr. Miner, Dr. VanOrman, and Dr. Yau.

Next meeting set for August 9, 2007
Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered three petitions.